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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.



## **OFFICIAL ACTION**

### ***Acknowledgment of Receipt***

Receipt of the Applicants' Response, to the Official Action dated May 13, 2005, and terminal disclaimer in compliance with 37 CFR 1.321(c) to overcome the obviousness-type double patenting rejection over U.S. Patent 6,375,978 (hereinafter the Kleiner '978 patent), which were filed on August 15, 2005, is acknowledged.

It should be mentioned however, that upon a further review of the prosecution history, it was discovered that a terminal disclaimer had already been filed on November 17, 2003, in compliance with 37 CFR 1.321(c), to overcome an obviousness-type double patenting rejection over the Kleiner '978 patent as set forth in the Official Action mailed August 14, 2003. As a result, a telephone call was made to the attorney of record, namely Mr. Edgar R. Cataxinos, Esq. on February 23, 2006, to notify the aforementioned of such.

### ***Status of Claims***

Claims 2, 4-9, 21 and 23-27 were canceled by a preliminary amendment filed on May 13, 2002. Claims 62 and 63 were canceled by an amendment filed on November 17, 2003 in response to the Official Action mailed on August 14, 2003. Claims 14, 17-20, 22, 28-33, 40, 42-46, 48-52, 54-55, 57-58 and 60-61 were rejoined in the Official Action mailed on May 13, 2005. Claims 46, 49 and 54 were canceled by an amendment filed on August 15, 2005. As a result, claims 1, 3, 10-20, 22, 28-45, 47-48, 50-53, 55-61 and 64 are currently pending and therefore examined herein on the merits for patentability.

***Claim Rejections - 35 U.S.C. § 102***

The following are quotations of the appropriate paragraphs of 35 U.S.C. § 102, which form the basis of the anticipation rejections as set forth under this particular section of the Official Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1, 11-14, 36-38, 40-45, 53, 56 and 64 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,024,842 (hereinafter the Edgren '842 patent).

For examination purposes, the aforementioned claims have been interpreted, consistent with the instant disclosure, as being drawn solely to a rate controlling membrane, notwithstanding the fact that said claims also recite an intended future use and a product-by-process of said claimed rate controlling membrane. The Edgren '842 patent likewise discloses a rate controlling membrane, wherein said rate controlling membrane is in the form of a subcoat coating composition comprising polyalkylene oxides (i.e., polyethylene glycols or polyethers) (column 1, lines 49-50; column 2, line 56-61; column 3, lines 56; column 5, lines 19, 24-27 and 68; column 6, lines 1-2 and 34; column 7, lines 25-50; column 9, lines 53-68; column 10, lines 1-8).

The abovementioned recitations of an intended future use (designated within said claims hereinbelow as being encompassed by parentheses) of said rate controlling membrane (i.e., for incorporation into an implantable drug delivery device in addition to various features of said implantable drug delivery device) will be given little probative patentable weight because the recitations occur in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 190 USPQ 15 (CCPA 1976); and *Kropa v. Robie*, 88 USPQ 478, 481 (CCPA 1951).

The abovementioned recitations of a product-by-process (designated within said claims hereinbelow as being encompassed by brackets) of said rate controlling membrane. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

For the reasons given above, claims 1, 11-14, 36-38, 40-45, 53, 56 and 64 of the instant application have been interpreted, consistent with the instant specification, as being directed solely to a rate controlling membrane as illustrated hereinbelow in greater detail:

Independent claim 1 recites:

A rate controlling membrane (for an implantable drug delivery device) [characterized by being subjected to an elevated temperature of about 30°C to about 5°C below the melting temperature of the membrane for a predetermined period of about 1-250 hours and subsequently incorporated into the drug delivery device].

Claim 11, which is dependent upon claim 1 discussed hereinabove, recites:

The rate controlling membrane according to claim 1 (wherein the membrane is positioned in sealing relationship with an internal surface of one end of an impermeable reservoir of a fluid-imbibing drug delivery device, wherein the impermeable reservoir contains a piston that divides the impermeable reservoir into a drug-containing chamber and a water-swellaable agent-containing chamber, wherein the water-swellaable agent-containing chamber is provided with an outlet which accommodates the membrane).

Claim 12, which is dependent upon claim 1 discussed hereinabove, recites:

The rate controlling membrane according to claim 1 (further comprising a drug-containing chamber).

Claim 13, which is dependent upon claim 1 discussed hereinabove, recites:

The rate controlling membrane according to claim 1 [wherein the elevated temperature is about 45 to about 80°C and the predetermined period is about 1 - 75 hours].

Independent claim 14 recites:

A rate controlling membrane (for an implantable drug delivery device) [characterized by being subjected to an elevated temperature of about 30°C to about 50°C below the melting temperature of the membrane polymer for a predetermined period of about 1 to 250 hours and subsequently incorporated into the delivery device wherein the membrane is cooled to ambient conditions before being incorporated into the delivery device].

Claim 36, which is dependent upon claim 11 discussed hereinabove, recites:

The rate controlling membrane according to claim 11 (wherein the drug-containing chamber comprises an opioid analgesic drug).

Claim 37, which is dependent upon claim 11 discussed hereinabove, recites:

The rate controlling membrane according to claim 11 (wherein the drug-containing chamber comprises an antiviral drug).

Claim 38, which is dependent upon claim 11 discussed hereinabove, recites:

The rate controlling membrane according to claim 11 (wherein the drug-containing chamber comprises an antineoplastic drug).

Independent claim 40 recites:

A rate controlling membrane (for an implantable drug delivery device) [characterized by being subjected to an elevated temperature of about 30°C to about 50°C below the melting temperature of the membrane polymer for a predetermined period of about 1 to 250 hours and subsequently incorporated into the delivery device wherein the membrane is allowed to relax at room temperature for about 12 hours to 7 days before being annealed].

Independent claim 41 recites:

A rate controlling membrane (for an implantable drug delivery device) [characterized by being subjected to an elevated temperature of about 52°C to about 72°C for a predetermined period of about 2 to 36 hours and subsequently incorporated into the drug delivery device].

Independent claim 42 recites:

A rate controlling membrane (for an implantable drug delivery device) [characterized by being subjected to an elevated temperature of about 52°C to about 72°C for a predetermined period of about 2 to 36 hours and subsequently incorporated into the delivery device wherein the membrane is cooled to ambient conditions before being incorporated into the delivery device].

Independent claim 43 recites:

A rate controlling membrane (for an implantable drug delivery device) [characterized by being subjected to an elevated temperature of about 52°C to about 72°C for a predetermined period of about 2 to 36 hours and subsequently incorporated into the delivery device, wherein the membrane is allowed to relax at room temperature for about 12 hours to 7 days before being subjected to an elevated temperature].

Independent claim 44 recites:

A rate controlling membrane (for an implantable drug delivery device) [characterized by being subjected to an elevated temperature of about 52°C to about 72°C for a predetermined period of about 2 to 36 hours and subsequently incorporated into the delivery device wherein during processing the membrane is dried to about 0 to about 1 % moisture content before being annealed and wherein the membrane is kept at about 0 to about 1% moisture content during annealing].

Independent claim 45 recites:

A rate controlling membrane (for an implantable drug delivery device) [characterized by allowing the membrane to relax at room temperature for about 12 hours to 7 days before being annealed; subjecting the membrane to an elevated temperature of about 52°C to about 72°C for a predetermined period of about 2 to 36 hours; and cooling the membrane to ambient conditions before being incorporated into the delivery device].

Independent claim 53 recites:

The rate controlling membrane (for an implantable drug delivery device) [characterized by being subjected to an elevated temperature of about 45°C to about 80°C for a predetermined period of about 1 to about 75 hours and subsequently incorporated into the drug delivery device].

Independent claim 56 recites:

A rate controlling membrane (for an implantable drug delivery device) [characterized by being subjected to an elevated temperature of about 55°C to about 75°C for a predetermined period of about 12 - 48 hours wherein the membrane comprises a material selected from the group consisting of a polyurethane and a polyether blocked amide copolymer].

Claim 64, which is dependent upon claim 12 discussed hereinabove, recites:

The rate controlling membrane according to claim 12, (wherein the drug containing chamber comprises leuprolide).



For examination purposes, the aforementioned claims have been interpreted, consistent with the instant disclosure, as being drawn solely to a rate controlling membrane, notwithstanding the fact that said claims also recite an intended future use and a product-by-process of said claimed rate controlling membrane. The Edgren '842 patent likewise discloses a rate controlling membrane, wherein said rate controlling membrane is in the form of a subcoat coating composition comprising polyalkylene oxides (i.e., polyethylene glycols or polyethers) (column 1, lines 49-50; column 2, line 56-61; column 3, lines 56; column 5, lines 19, 24-27 and 68; column 6, lines 1-2 and 34; column 7, lines 25-50; column 9, lines 53-68; column 10, lines 1-8).

The abovementioned recitations of an intended future use (designated within said claims hereinbelow as being encompassed by parentheses) of said rate controlling membrane (i.e., for incorporation into an implantable drug delivery device in addition to various features of said implantable drug delivery device) will be given little probative patentable weight because the recitations occur in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 190 USPQ 15 (CCPA 1976); and *Kropa v. Robie*, 88 USPQ 478, 481 (CCPA 1951).

The abovementioned recitations of a product-by-process (designated within said claims hereinbelow as being encompassed by brackets) of said rate controlling membrane. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product

of the prior art, the claim is unpatentable even though the prior product was made by a different process.” See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

2. Claims 1, 3, 10-16, 34, 36-45, 47, 53, 56, 59 and 64 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent 5,728,396 (hereinafter the Peery ‘396 patent).

For examination purposes, the aforementioned claims have been interpreted, consistent with the instant disclosure, as being drawn to a rate controlling membrane, notwithstanding the fact that said claims also recite an intended future use and a product-by-process of said claimed rate controlling membrane. The Peery ‘396 patent likewise discloses a rate controlling membrane, wherein said rate controlling membrane is in the form of a plug and comprises a polyurethane or a polyether blocked polyamide copolymer (column 2, lines 48, 58-59 and 67; column 3, line 35; column 4, lines 21, 60 and 63; column 5, lines 1-2; column 6, line 43-60; column 10, line 40; column 12, line 61; column 13, line 6; column 14, lines 2, 5, 20, 27, 46, 54, 56 and 58; column 15, line 21).

The abovementioned recitations of an intended future use (designated within said claims hereinbelow as being encompassed by parentheses) of said rate controlling membrane (i.e., for incorporation into an implantable drug delivery device in addition to various features of said implantable drug delivery device) will be given little probative patentable weight because the recitations occur in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps

or structural limitations are able to stand alone. See *In re Hirao*, 190 USPQ 15 (CCPA 1976); and *Kropa v. Robie*, 88 USPQ 478, 481 (CCPA 1951).

The abovementioned recitations of a product-by-process (designated within said claims hereinbelow as being encompassed by brackets) of said rate controlling membrane. “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

With respect to claims 3, 10, 15, 16, 34, 39, 47 and 59 of the instant application:

Claim 3, which is dependent upon claim 1 discussed hereinabove, recites:

The rate controlling membrane according to claim 1 wherein the membrane comprises a polyurethane or a polyether blocked amide copolymer.

Claim 10, which is dependent upon claim 3 discussed hereinabove, recites:

The rate controlling membrane according to claim 3 wherein the membrane comprises a polyurethane.

Claim 15, which is dependent upon claim 3 discussed hereinabove, recites:

The rate controlling membrane according to claim 3 [wherein the elevated temperature is about 52 to about 72°C and the predetermined period is about 2 - 36 hours].

Claim 16, which is dependent upon claim 10 discussed hereinabove, recites:

The rate controlling membrane according to claim 10 [wherein the elevated temperature is from about 55 to about 75°C and the predetermined period is about 12 - 48 hours].

Claim 34, which is dependent upon claim 1 discussed hereinabove, recites:

The rate controlling membrane according to claim 1 wherein the membrane comprises a polyether blocked amide copolymer.

Claim 39, which is dependent upon claim 10 discussed hereinabove, recites:

The rate controlling membrane according to claim 10 [wherein the membrane is allowed to relax at room temperature for about 12 hours to 7 days before being annealed].

Claim 47, which is dependent upon claim 10 discussed hereinabove, recites:

The rate controlling membrane according to claim 10 [wherein the elevated temperature is from about 50 to about 80°C and the predetermined period is about 4 hours - to about 72 hours].

Claim 59, which is dependent upon claim 3 discussed hereinabove, recites:

The rate controlling membrane according to claim 3 wherein the membrane comprises a polyether blocked amide copolymer.

### ***Claim Rejections - 35 U.S.C. § 103***

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 17-20, 22, 28-33, 35, 48-52, 55, 57, 58, 60 and 61 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Edgren '842 patent in view of Peery '396 patent.

With respect to claims 17-20, 22, 28-33, 48-52, 55, 57 and 58 of the instant application, the Edgren '842 patent teaches a method of processing a rate controlling membrane, which is in the form of a polymeric subcoat coating composition comprising polyalkylene oxides (i.e., polyethylene glycols or polyethers) (column 1, lines 49-50; column 2, line 56-61; column 3, lines 56; column 5, lines 19, 24-27 and 68; column 6, lines 1-2 and 34; column 7, lines 25-50; column 9, lines 53-68; column 10, lines 1-8), wherein said method comprises: (a) bringing said rate controlling membrane up to a pre-selected annealing temperature; (b) keeping said rate controlling membrane at the pre-selected annealing temperature for a pre-selected period of time; (c) cooling said rate controlling membrane to room temperature; and (d) incorporating said rate controlling membrane into an osmotic drug delivery device (column 8, lines 3-20). The Edgren '842 patent also teaches that said rate controlling membrane is "brought up to a pre-selected [annealing] temperature," which implies that said rate controlling membrane existed at ambient conditions or room temperature (i.e., from about 20°C to about 25°C) for an unspecified period of time prior to subjecting said rate controlling membrane to the pre-selected annealing temperature (column 8, lines 3-20). This is particularly the case in light of the fact that the Edgren '842 patent teaches that in a preferred embodiment, the pre-selected annealing temperature is from about 20°C (i.e., ambient conditions or room temperature) to about 75°C for a pre-selected period of time of about 5 hours to about 90 hours (column 8, lines 19-20).

With respect to claims 55, 60 and 61 of the instant application, although the Edgren '842 patent teaches that the method of processing said rate controlling membrane: (a) increases the

density of the polymeric subcoat coating composition; (b) improves the heat resistance and stability of said rate controlling membrane when exposed to higher temperatures; (c) improves the impact strength of said rate controlling membrane; and (d) enhances the mechanical integrity of said rate controlling membrane (column 8, lines 3-20 and 27-31); the Edgren '842 patent does not explicitly teach a rate controlling membrane that exhibits decreased variability of water uptake from membrane to membrane, as claimed in claims 55 and 61, as well as more stable water uptake and more stable water permeability in comparison to a non-annealed rate controlling membrane, as claimed in claim 60. However, while the Edgren '842 patent does not explicitly teach the instantly claimed property of water uptake stability it is well within the purview of the skilled artisan to determine the optimal amount of water uptake variability, or a corresponding lack thereof, by systematically adjusting the times, temperatures and relative ratios of the various polymeric components within the method of processing said rate controlling membrane during the course of routine experimentation. One of ordinary skill in the art at the time the instant application was filed would have been motivated to systematically adjust the times, temperatures and relative ratios of the various polymeric components within the method of processing said rate controlling membrane, during the course of routine experimentation to obtain a resultant rate controlling membrane possessing a desired water uptake stability for incorporation into an osmotic drug delivery device. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955). "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges

is the optimum combination of percentages.” See *Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

With respect to claims 22, 30 and 35, the Edgren ‘842 patent does not explicitly teach a rate controlling membrane comprising a polyurethane or a polyether blocked polyamide copolymer. However, the Peery ‘396 patent teaches a rate controlling membrane, wherein said rate controlling membrane is in the form of a plug and comprises a polyurethane or a polyether blocked polyamide copolymer (column 6, lines 43-60). It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the method of the Edgren ‘842 patent to include polyurethanes and polyether blocked polyamide copolymers within said rate controlling membrane, especially in light of the fact that the Edgren ‘842 patent teaches rate controlling membranes comprising hydrophilic polymers, such as polyalkylene oxides in combination with other hydrophilic polymers (column 7, lines 25-53), such as polyurethanes, polyamides, polyalkylene oxides, and copolymers thereof, as taught in U.S. Patent 4,160,020 (hereinafter the Ayer ‘020 patent), which is explicitly referenced within the Edgren ‘842 patent (column 7, lines 52-53). One of ordinary skill in the art at the time the instant application was filed would have been motivated to incorporate hydrophilic polymers, such as polyurethanes and polyether blocked polyamide copolymers, in combination with polyalkylene oxides within said rate controlling membrane so as to aid in transporting fluid from the environment of use, as reasonably suggested by the Edgren ‘842 patent. One of ordinary skill in the art at the time the instant application was filed would have had a reasonable expectation of success in incorporating polyurethanes and polyether blocked polyamide copolymers within said rate controlling membrane, especially in light of the fact that polyurethanes have a melting point of about 80°C to about 110°C,

which is approximately 5°C to 30°C above the pre-selected annealing temperature of the Edgren '842 patent (column 8, lines 19-20).

### ***Conclusion***

Claims 1, 3, 10-20, 22, 28-45, 47-48, 50-53, 55-61 and 64 are rejected because the claimed invention would have been anticipated and/or prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, is disclosed in and/or would have been reasonably suggested by the teachings of the cited prior art references.

### ***Remarks***

The following is a list of prior art patents and publications, both foreign and domestic, made of record and considered pertinent to the applicant's disclosure, but are not however currently relied upon in construing the claim rejections as set forth herein:

Japanese Application Publication 10-290849 (hereinafter the Umezawa '849 publication);  
U.S. Patent 4,160,020 (hereinafter the Ayer '020 patent) (column 9, lines 3-7; column 10, lines 24-26, 36-39, 49-50 and 58-60).

### ***Contact Information***


Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Sreenivasan Padmanabhan can be reached at 571-272-0629. The central fax number for the USPTO is 571-273-8300.



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